

D-3090.
Appl. No. 10/748,761
Reply to Office Action of 11/13/06

Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 2B. This sheet, which includes Figs. 1, 2A and 2B, replaces the original sheet including Figs. 1, 2A and 2B. In Figure 2B, previously omitted element 58 has been added.

Attachment: Replacement Sheet
Annotated Sheet Showing Changes

REMARKS

The above-identified application has been carefully reviewed in light of the Examiner's communication mailed November 13, 2006.

Fig. 2B has been amended to include the reference numeral 58 referring to the open interior space as shown in Fig. 2A and 2D. Thus, the amendment to Fig. 2B is supported by Figs. 2A and 2D and the specification, for example, at page 12, lines 2-16, as originally filed. Therefore, no new matter is added by this amendment to Fig. 2B.

The first full paragraph of page 12 of the present specification has been amended to include the following sentence: "As shown in Fig. 2b, the open interior space 58 defined by the outer peripheral portion 56 remains open when the appliance 54 is placed in the body region." This amendment is fully supported by the present specification, for example, the first full paragraph on page 12, as originally filed, and Figs. 2A and 2D of the drawings, as originally filed. Therefore, no new matter is added by this amendment to the specification.

Without conceding the correctness of any of the Examiner's rejections, applicant has amended the claims seeking to facilitate prosecution of the above-identified application and to obtain an early allowance. Applicant expressly reserves the right to seek patent protection for the original claims and for any other claims supported by the above-identified application in one or more related applications.

Specifically, independent claim 1 has been amended to recite that the body portion and the end portions of the appliance define an interior open space and that the appliance is structured to take on a deployed configuration when located

within a vessel or other body region such that the interior open space remains open. Other minor amendments have been made to claim 1 for clarity. Claim 3 has been amended to delete the word "oblong". Claim 13 has been cancelled, without prejudice, to be consistent with the amendments to claim 1. Independent claim 14 has been amended in a manner similar to claim 1. Thus, claim 14 provides that the body portion and end portions of the member together define an interior open space and that releasing the end portions from being held or secured together allows the member to expand within the body region so that the interior open space remains open.

In addition, independent claim 16 has been amended to provide a method in which an elongated member having a desired stiffness and resiliency and comprising a body portion and end portions spaced apart by the body portion, with the body portion and the end portions together defining an interior open space is provided. The elongated member is implanted submucosally into walls of a vessel of a human or animal in alignment with a longitudinal axis so that the interior open space remains open. Claim 17 has been amended to be consistent with independent claim 16. New claims 18, 19 and 20 have been added and are directed to embodiments for which patent protection is sought.

Each of the amendments and the new claims is fully supported by the present specification and drawings, for example, page 12, line 2 to page 13, line 2; and Figs. 2a-2e and 3a-3c. Note that Figs. 3a, 3b and 3c show an apparatus 60 which is similar to the embodiment shown in Figs. 2a-2e, with the primary difference being that apparatus 60 is made of substantially mesh construction. Otherwise apparatus 60 (Figs. 3a-3c) is substantially the same as apparatus 50 (Figs. 2a-2e).

Applicant acknowledges the holding of the Examiner that claims 3, 7-12 and 17 are to be withdrawn as being directed to a non-elected invention. Applicant respectfully requests the Examiner to reconsider this holding with regard to claim 3 and claim 17. Claim 3, as noted above, has been amended to be consistent with claim 1 by deleting the word "oblong". Claim 17 has been amended to be consistent with claim 16. Thus, applicant respectfully requests that claims 3 and 17, as amended, be considered together with independent claims 1 and 16, respectively in the above-identified application.

Claims 1, 2, 4 and 5 have been rejected under 35 U.S.C. 102(b) as being anticipated by Khosravi et al (U.S. Patent 5,618,299). Claims 6 and 14-16 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al in view of Roth (U.S. Patent 6,406,490). Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al as applied to claim 1 and further in view of Zafrir-Pachter et al (U.S. Patent Publication 2004/0010308). Applicant traverses each of these rejections as it pertains to the present claims 1-6 and 14-20.

In claim 1, an apparatus for maintaining patency of a vessel or other region of a human or animal body is provided. The apparatus comprises an appliance comprising a body portion and end portions spaced apart by the body portion. The body portion and the end portions together define an interior open space, and may be made of mesh construction (claim 18). The appliance is structured to take on a deployed configuration when located within a vessel or other body region of a human or animal body such that (a) the interior open space remains open, (b) the end portions are spaced apart from each other by other

than the body portion, the end portions overlap each other, or the end portions directly contact each other, and (c) the appliance exerts a force on the vessel or other body region to maintain the region substantially open or unobstructed or to cause the region to be maintained substantially open or unobstructed.

Independent claim 14 is directed to a method for maintaining patency of, or for causing to become patent, open or unobstructed, a body region of a human or an animal. The method comprises providing a flat or pre-curved member having a body portion and end portions spaced apart from the body portion with the body portion and the end portions together defining an interior open space. The body portion and the end portions may be made of mesh construction (claim 19). The end portions of the flat or pre-curved member are pulled together to form a folded configuration. The end portions are held or temporarily secured together. The member in the folded configuration is placed into the body region to be treated. The end portions are released from being held or secured together, thereby allowing the member to expand within the body region so that the interior open space remains open.

In independent claim 16, a method for maintaining patency of or for causing to become patent, open or unobstructed, a vessel of a human or animal is provided. The method comprises providing an elongated member having a desired stiffness and resiliency, with the member comprising a body portion and end portions spaced apart by the body portion. The body portion and the end portions together define an interior open space, and may be made of mesh construction (claim 20). The elongated member is implanted submucosally into walls of the vessel in alignment

with a longitudinal axis so that the interior open space remains open.

Khosravi et al discloses a ratcheting stent involving an intravascular stent including a cylindrical sheet having overlapping edges that interlock.

Khosravi et al does not disclose, teach or suggest the present invention. For example, Khosravi et al does not disclose, teach or even suggest an appliance comprising a body portion and end portions spaced apart by the body portion such that together the body portion and the end portions define an interior open space, as recited in the present claims. Moreover, Khosravi et al does not disclose, teach or even suggest an appliance structured to take on a deployed configuration when located in a vessel or other body region of a human or animal body such that the interior open space remains open, as recited in the present claims.

Therefore, applicant submits that the present claims, that is claims 1-6 and 14-20 are not anticipated by Khosravi et al under 35 U.S.C. 102(b).

Zafir-Pachter et al discloses an implantable device useful for implantation in the common carotid artery at its bifurcation with the internal carotid artery for reducing the risk of stroke. Zafir-Pachter et al discloses that the device includes a base element for anchoring the device in the artery, and a deflector element for covering the inlet of the internal carotid artery. Specifically, Zafir-Pachter et al discloses that the deflector element is formed with openings of a size and configuration to deflect emboli in the blood to the external carotid artery without blocking blood flow through the external or internal carotid arteries. Although Zafir-Pachter et al

discloses one area of a meshed structure 21 is an open zone 27, this document makes clear that this open zone is covered with a deflecting filtering element 40 when the device is deployed in the common carotid artery, as intended. See paragraphs 0069 and 0075 of Zafrir-Pachter et al.

The device disclosed by Zafrir-Pachter et al without the open zone 27 covered with a deflecting filtering element would be inoperable to achieve its intended result, that is the removing of emboli from the blood entering the base element. In short, the open zone of the Zafrir-Pachter et al device in use in the common carotid artery must be covered. This is in direct contrast to the present invention in which the interior open space remains open when placed in a vessel or other body region. In fact, to a large extent, Zafrir-Pachter et al teaches clearly, directly and expressly away from the present invention.

In view of the above, the combination of Khosravi et al and Zafrir-Pachter et al provides no basis for combining these references for any purpose, let alone for the purpose of making obvious the present invention. Neither Khosravi et al nor Zafrir-Pachter et al even suggests an apparatus structured so that when placed in a vessel or other body region the interior open space defined by the body portion and end portions of the apparatus remains open. As noted above, Zafrir-Pachter et al actually teaches away from the present invention.

Therefore, applicant submits that the present claims, including claims 1-6 and 14-20, are unobvious from and patentable over Khosravi et al in view of Zafrir-Pachter et al under 35 U.S.C. 103(a).

With regard to Roth, the Examiner contends that Roth discloses a stent for maintaining patency of a blood vessel with radiused ends. See column 6, lines 24 to 28.

However, Roth does not supply the deficiencies apparent in the teachings of Khosravi et al and Zafrir-Pachter et al. For example, like the other documents, Roth does not disclose, teach or even suggest an appliance comprising a body portion and end portions spaced apart by the body portion with the body portion and the end portions together defining an interior open space and the appliance being released within the body region so that the interior open space remains open, as recited in independent claim 14; or implanting an elongated member submucosally into walls of the vessel in alignment with a longitudinal axis so that the interior open space defined by the body portion and the end portions remains open, as recited in independent claim 16.

In view of the above, applicant submits that the present claims, that is claims 1-6 and 14-20, are unobvious from and patentable over Khosravi et al, Zafrir-Pachter et al and/or Roth alone or in any combination under 35 U.S.C. 103(a).

Each of the present dependent claims is separately patentable of the prior art. For example, none of the prior art, taken singly or in any combination, disclose, teach or even suggest the present apparatus and methods having the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. 102(b) and 103(a). Therefore, applicant submits that the present claims, that is

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claims 1-6 and 14 to 20, are allowable and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call applicant's attorney at the telephone number given below.

Respectfully submitted,

Date: _____

FEB. 13, 2007



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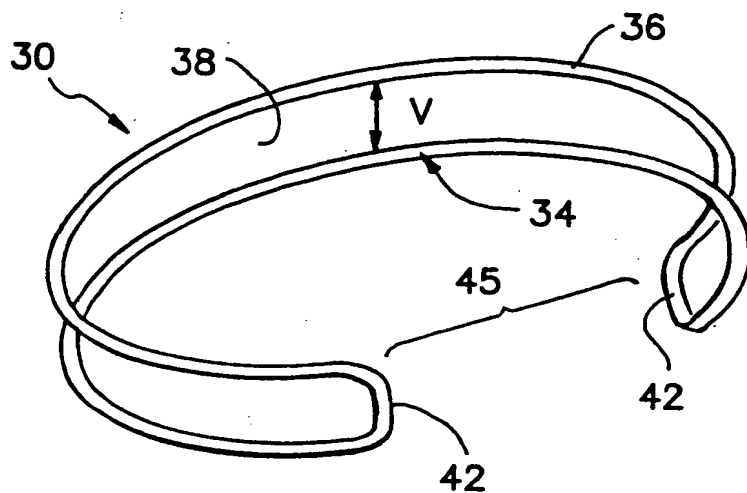
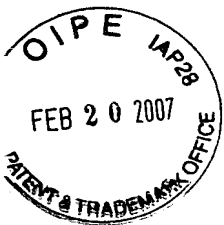


FIG. 1

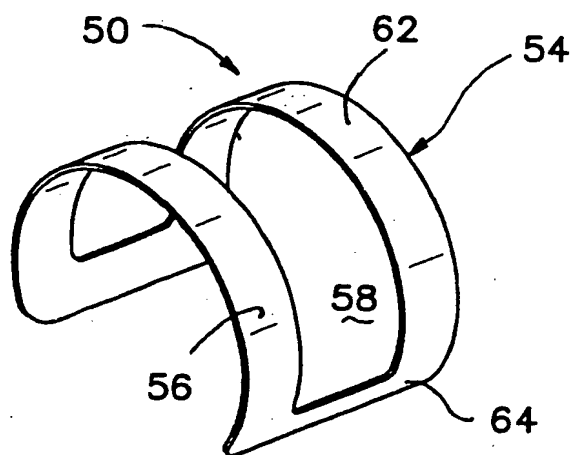


FIG. 2A

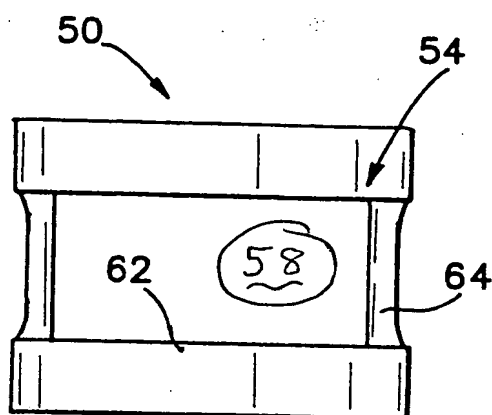


FIG. 2B